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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,919	01/10/2004	Syde A. Taheri	VNUS.017A	8233

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EXAMINER	
DAWSON, GLENN K	
ART UNIT	**PAPER NUMBER**
3731	

NOTIFICATION DATE	DELIVERY MODE
11/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/754,919	TAHERI, SYDE A.	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *8-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 20-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,20-23,27-29,31,33-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroeder, et al.-6254635.

Schroeder discloses a venous occlusive stent having a bioabsorbable stent body and bioabsorbable means (leaflets) for blocking blood flow past the stent. See col. 8 lines 16-19 and all the figures. The leaflets have portions which are extend from one end (which could be proximal or distal) and extend towards the center section of the stent body.

Claims 1-4,28,29 and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Devellian-2005/0070952.

Devellian discloses a bioabsorbable stent 32 and a bioabsorbable closure 21. The stent is a hollow tube. The device though placed in an LAA, if placed in a vessel

would act to occlude blood flow through the vessel. The position of 21 could be everted and is therefore adjustable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5,24,30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder, et al.-'635 in view of Duran-'297.

Schroeder discloses the invention as claimed with the exception of the specific type of bioabsorbable material. Duran discloses that polylactic acid was a known bioabsorbable material. It would have been obvious to have formed the bioabsorbable portions of Schroeder's device out of polylactic acid as Duran discloses that it is a good material for forming a bioabsorbable structure because it has a predictable degradation rate.

Claims 5,24,29,30,33-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devellian-'952 in view of Duran-'297

Devellian discloses the invention as claimed with the exception of the bioabsorbable material being polylactic acid. Duran discloses such a material. It would have been obvious to have formed the bioabsorbable portions of Devallian's device out

of polylactic acid as Duran discloses that it is a good material for forming a bioabsorbable structure because it has a predictable degradation rate. To have made the side wall of the stent body a non-filtering material would have been obvious in order to prevent fluid or embolic material from entering the interior of the stent body which could increase internal pressure and risk expulsion or damage to the interior of the LAA.

Claims 1-4,20-23,27-29,31,33-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik, et al.-2004/0186558 in view of Schroeder, et al.-'635.

Pavcnik discloses an absorbable venous occlusive stent including a bioabsorbable stent body and leaflets which prevent passage of blood through the lumen of the stent body. However, the leaflets being a bioabsorbable material is not disclosed. However, Schroeder discloses that it was known to manufacture a similar device using bioabsorbable leaflets. It would have been obvious to have made the leaflets of Pavcnik out of a bioabsorbable material so that the device would either completely dissolve after serving its intended purpose, or depending on the degradation rate, allow for natural tissue to take its place and eliminate the need for a surgical procedure to remove it later on.

Claims 1-4,20-23,27-29,31,33-37 and 39 are rejected under 35 U.S.C. 102(b) as anticipating, or alternatively under 35 U.S.C. 103(a) as being unpatentable over Dimateo-6440164 in view of Schroeder, et al.-'635.

Dimateo discloses a device including a bioabsorbable stent body with a lumen and bio-absorbable blocking means comprising bioabsorbable valve leaflet frames. As at least a portion of each of the leaflets is bioabsorbable, the examiner contends that a

bioabsorbable portion blocks the blood flow. Even though 112 6th is being invoked, the examiner contends that the prior art meets this limitation as the structure would be an equivalent because the structures have substantially the same result, (blocking blood flow), do it in substantially the same manner, (physically closing off the lumen of the stent), and culminate in a substantially equivalent result (closure frame is absorbed and the valve itself is replaced by body tissue cells). The blocking means attaches at one end of the stent but extends to a location between the ends. The valve moves from a position allowing blood to flow through the stent and a closed position blocking blood flow therethrough.

If this is not persuasive, then the examiner turns to Schroeder which discloses a similar device using bioabsorbable leaflets. It would have been obvious to have made the leaflets of Dimateo out of a bioabsorbable material so that the device would either completely dissolve after serving its intended purpose, or depending on the degradation rate, allow for natural tissue to take its place and eliminate the need for a surgical procedure to remove it later on.

Claims 5,24,30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimateo-'164 in view of Schroeder, et al.-'635, as applied above, and further in view of Duran-'297.

Dimateo as modified by Schroeder makes obvious the invention as claimed with the exception of the specific type of bioabsorbable material. Duran discloses that polylactic acid was a known bioabsorbable material. It would have been obvious to have formed the bioabsorbable portions of Dimateo's device out of polylactic acid as Duran

discloses that it is a good material for forming a bioabsorbable structure because it has a predictable degradation rate.

Claims 6,7,25,26,32 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo, et al.-'164 in view of Schroeder, et al.-'635, as applied above, and further in view of Soetokno, et al.-2002/0143387.

DiMatteo as modified by Schroeder makes obvious the invention as claimed with the exception of the drawstring closure. Soetikno discloses another elongated tubular stent and a drawstring located at one end. This drawstring can be incorporated into any stent. It would have been obvious to have added a drawstring to the stent of DiMatteo in order to allow it to be easily re-positioned. When combined, the drawstring could be used to pull the end of the stent tight enough to prevent or substantially stop the flow of blood through the stent since the modified stent includes an impervious layer over the stent frame.

Response to Arguments

Applicant's arguments filed 11-01-2007 have been fully considered but they are not persuasive.

Applicant argues that the leaflets are not bioabsorbable, and the frame cannot read on the bioabsorbable means. The examiner contends that the leaflets including the bioabsorbable frame together constitute the claimed bioabsorbable means because the structure as a whole acts to block blood flow past it and a portion is bioabsorbable. However, if this is not persuasive, the examiner has provided a teaching reference for

using bioabsorbable leaflets. Using this combination, all of the elements of the rejected claims are met.

Devellian is formed of a material which can be bioabsorbable and which expands by itself or by a balloon to contact and seal with the inner surface of the LAA. The material therefore substantially conforms to the wall f the LAA. The device could easily be placed in the vasculature, either into an aneurysm, or placed into a linear section of an artery. The placement could either be at a location where the flange could abut the vascular wall, or could be placed while performing an anastomosis and placed such that the flange were placed between abutting portions of end walls of two vascular segments and then the device could be adhesively held in place, or held there using sutures or other connection means. In any event, the examiner contends that the device could be placed into the vasculature and act to occlude blood flow past it.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
21 November 2007